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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,232	08/15/2001	Xianqiang Li	CLON075CON	3812
41064	7590	06/23/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES)			WILDER, CYNTHIA B	
200 MIDDLEFIELD ROAD, SUITE 200			ART UNIT	
MENLO PARK, CA 94025			PAPER NUMBER	

1637

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

**Office Action Summary****Application No.**

09/931,232

**Applicant(s)**

LI ET AL.

**Examiner**

Cynthia B. Wilder, Ph.D.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/7/2002</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's preliminary filed on 8/15/2001 is acknowledged. Claims 1-5 have been canceled. Claims 6-22 are pending.

#### ***Election/Restrictions***

2. Applicant's election of Group I, claims 6-17 with traverse in the reply filed on 5/8/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 18-22 have been withdrawn from consideration as being drawn to a non-elected invention.

#### ***Objections***

3. The specification and claims 6 and 10 are objected to because of the following informalities:
  - (a) Claim 6 is objected to because claim 6 depends from claim 1 which has been canceled. It is suggested amending claim 6 to comprise the limitations from canceled claim 1. Appropriate correction is required.
  - (b) The specification and claim 10 is objected to because the designation for the sequences "SEQ ID No." at pages 16 and 26 of the specification is improper. It is suggested changing "SEQ ID No." to --SEQ ID No:--.

#### ***Claim Rejections - 35 USC § 112 first paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 6-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fusion protein comprising GFP or EGFP and MODC<sub>376-461</sub>, MODC<sub>376-456</sub> or MODC<sub>422-461</sub> and specific disclosed variants therein, it does not reasonably provide enablement for any and all fluorescent fusion proteins with a half or less than 10 hours, or for fusion proteins comprising MODC whose sequences are not disclosed in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The first paragraph of section 112 requires the specification describe how to make and use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue (See *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988)). These factors include, but are not limited to: (1) quantity of experimentation necessary, (2) the amount of direction or guidance presented in the specification, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the unpredictability of the art and (8) the breadth of the claims.

The specification teaches a fusion protein comprising GFP or EGFP fused to a PEST sequence-containing portion of a c-terminus of murine onithine decarboxylase (MODC), such as e.g., MODC<sub>376-461</sub>, MODC<sub>376-456</sub> or MODC<sub>422-461</sub> and specific disclosed variants therein. The specification however does not teach any other types of fluorescent proteins, or any other types

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of sequences fused to GFP or EGFP proteins, besides those disclosed therein which would predictably results in the specified half-life. The specification provides insufficient guidance and directions to enable any and all GFP and EGFP proteins having a half-life of no more than about 10 hours. Nowhere in the examples does the specification provide information for one of skill in the art to isolate any fusion protein comprising a fluorescent protein said fusion protein having a half life of no more than 10 hours. The specification does not disclose an isolated nucleic acid as claimed that bears a reasonable correction to the entire scope of the claims. Therefore, one skilled in the art would not know how to make or use the claimed nucleic acid using the large number of undisclosed isolated nucleic acid molecules without undue experimentation.

***Claim Rejections - 35 USC § 112 second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 8, 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 7 is indefinite for the abbreviations EGFP, ECFP and EYFP because abbreviations often have more than one meaning in the art. It is suggested inserting the full name of the abbreviations in the art.

(b) Claims 8 and 9 are indefinite for the abbreviation PEST because abbreviations often have more than one meaning in the art. It is suggested inserting the full name of the abbreviations in the art.

***Claim Rejections - 35 USC § 102(b)***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6, 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Moradpour et al. (Virology, vol. 222, pages 51-63, 1993, reference AE on form-1449 of 2/7/2002). Regarding claim 6, 11-17, Moradpour et al teach a method of assay activation or deactivation of translational elements by transfecting cells with a vector which encodes luciferase, a transient fluorescent protein having a half-life of less than 10 hours, and detecting the amount of fluorescent protein which is expressed by detecting the amount of fluorescence in the cells.

***Conclusion***

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

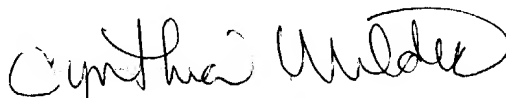
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
CYNTHIA WILDER  
PATENT EXAMINER  
6/21/2004